

Express Mail No. EV 330857135

PATENT

Mailed: August 19, 2003

Attorney Docket No.: 015280-257300
DHHS Ref. E-148-1998/1-US-04

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

GEORGE N. PAVLAKIS

Application No.:

Filed: Herewith

For: MOLECULAR CLONES WITH
MUTATED HIV GAG/POL, SIV GAG
AND SIV ENV GENES

Examiner:

Art Unit:

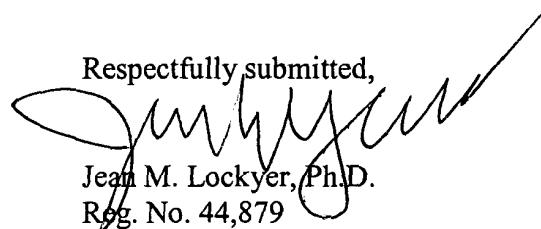
INFORMATION DISCLOSURE
STATEMENT
UNDER 37 CFR §1.97 AND §1.98

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants bring to the Examiner's attention the related patent application, U.S. Serial No. 09/872,733 filed June 1, 2001, which is relied upon for an earlier filing date under 35 U.S.C. §120. Applicants respectfully request that the references supplied in compliance with 37 C.F.R. §1.97 in said parent application, as well as those cited during its examination, be made of record. For the convenience of the Examiner, copies of the Information Disclosure Statements dated July 16, 2001, October 15, 2001 and January 31, 2003, as well as the forms PTO-1449 and PTO/SB/08B, filed in the parent application are attached. Copies of the documents will be found in said parent application.

Respectfully submitted,



Jean M. Lockyer, Ph.D.
Reg. No. 44,879

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
(415) 576-0200
Fax (415) 576-0300
JML/mcd - 60019445 v1

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

PATENT
Attorney Docket No.: 015280-257100US

Assistant Commissioner for Patents
Washington, D.C. 20231

On 31 Jan. 2003

TOWNSEND and TOWNSEND and CREW LLP

By: Malinda Adams

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

George N. Pavlakis

Application No.: 09/872,733

Filed: June 1, 2001

For: MOLECULAR CLONES WITH
MUTATED HIV GAG/POL, SIV GAG
AND SIV ENV GENES

Examiner: Dave Trong Nguyen

Art Unit: 1632

SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT UNDER 37
CFR §1.97 and §1.98

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The reference cited on attached form PTO/SB/08B is being called to the attention of the Examiner. A copy of the reference is enclosed.

Also enclosed is a copy of the Search/Examination report issued in a corresponding PCT application.

It is respectfully requested that the cited reference be expressly considered during the prosecution of this application, and the reference be made of record therein and appear among the "references cited" on any patent to issue therefrom.

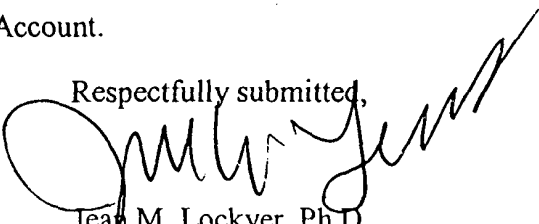
As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no

representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

This IDS is being filed before the mailing date of the final Office Action or Notice of Allowance.

Please charge the IDS fee to Deposit Account No. 20-1430 in accordance with the accompanying Fee Transmittal PTO/SB/17. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,



Jean M. Lockyer, Ph.D.
Reg. No. 44,879

TOWNSEND and TOWNSEND and CREW LLP
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JML:mcd

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|------------------------|-----------------|
| Attorney Docket Number | 015280-257100US |
|------------------------|-----------------|

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

PATENT

Docket No. 2026-4287US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | | |
|---------------------|----------|---|--|
| Applicant(s) | : | George Pavlakis | Group Art Unit: Beena Puri, Ph.D. |
| Serial No | : | 09/872,733 | Examiner: 1633 |
| Filed | : | June 1, 2001 | |
| For | : | MOLECULAR CLONES WITH MUTATED HIV GAG/POL, SIV GAG AND SIV ENV GENES | |

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

COMMISSIONER FOR PATENTS
Washington, D.C. 20231

Sir:

This Supplemental Information Disclosure Statement is filed in accordance with 37 C.F.R. §§1.56, 1.97 and 1.98. The items listed on Form PTO-1449, a copy of which is enclosed, may be deemed to be pertinent to the above-identified application and are made of record to assist the Patent and Trademark Office in its examination of this application. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teaching.

1. ☐ For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, an English language translation of that item or a portion thereof or a concise explanation of the relevance of that item is enclosed:

2. ☐ For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, a concise explanation of the relevance of that item is incorporated in the specification of the above-identified application.
3. ☐ Any copy of the items listed on the enclosed copy of Form PTO-1449 that is not enclosed with this Information Disclosure Statement was previously cited by or submitted to the Patent and Trademark Office in application Serial No. _____, filed _____.

4. ☒ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with:
- ☐ 37 C.F.R. §1.97(b)(1), within three months of the filing date of the above-identified application for filing date of the continued prosecution application filed on _____; or
 - ☐ 37 C.F.R. §1.97(b)(2), within three months of the date of entry into the national stage as set forth in §1.491 in an international application; or
 - ☒ 37 C.F.R. §1.97(b)(3), before the mailing date of a first Office Action on the merits, whichever event occurred last.
5. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a Notice of Allowance (where there has been no prior final action), and is accompanied by one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below.
6. ☐ A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a notice of allowance (where there has been no prior final action):
- ☐ A check in the amount of \$240.00 is enclosed in payment of the fee.
 - ☐ Charge the fee to Deposit Account No. 13-4500. Order No. _____. A
DUPLICATE COPY OF THIS SHEET IS ATTACHED.
7. ☐ A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(d), after the mailing date of a final action or a notice of allowance, whichever comes first, but before payment of the issue fee, and is accompanied by:
- a. ☐ one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below; and
 - b. ☐ the attached petition requesting consideration of this Information Disclosure Statement; and
 - c. ☐ the fee due under 37 C.F.R. §1.17(i)(1) which is paid as set forth in paragraph 10 below.
8. ☐ A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with:
- a. ☐ 37 C.F.R. §1.313(b)(3), after the issue fee has been paid and information cited in this Information Disclosure Statement may render at least one claim unpatentable and is accompanied by the attached Petition To Withdraw Application From Issue;
 - b. ☐ 37 C.F.R. §1.313(b)(5), after the issue fee has been paid and information cited in this Information Disclosure Statement is to be considered in a Continuation application upon abandonment of the instant application and is accompanied by the attached Petition To withdraw Application From Issue.
 - c. ☐ The fee due under 37 C.F.R. §1.17(i)(1) is paid as set forth in paragraph 10 below.

9. ☐ I hereby certify that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

☐ I hereby certify that no item of information in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after make reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

10. ☐ A check in the amount of \$130.00 is enclosed in payment of the fee due under C.F.R. §1.17(i)(1).

☐ Charge the fee due under C.F.R. §1.17(i)(1) to Deposit Account No. 13-4500. Order No. _____ A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

☒ The Assistant Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 13-4500. Order No. 2026-4287US1. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,
MORGAN & FINNEGAN, L.L.P.

Dated: October 15, 2001

By: _____

Mary J. Morry
Registration No. 34,398

CORRESPONDENCE ADDRESS:

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(212) 751-6849 Facsimile

FORM: IDS.NY
Rev. 05/26/98

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|--|----------------------|----------------------------------|---------------------------|--------------|------------------|--------------------|
| FORM PTO-1449 INFORMATION DISCLOSURE CITATION | | Attorney Docket: 2026-4287US1 | Serial No.: 09/872,733 | | | |
| | | Applicant: George Pavlakis | | | | |
| | | Filing Date: June 1, 2001 | Group Art Unit: 1633 | | | |
| U.S. PATENT DOCUMENTS | | | | | | |
| Examiner Initial | Patent Number | Issue Date | Name | Class | Sub-Class | Filing Date |
| | | | | | | |

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|---------------------------------|----------------------|-------------------|----------------|--------------|------------------|--|
| FOREIGN PATENT DOCUMENTS | | | | | | |
| Examiner Initial | Patent Number | Issue Date | Country | Class | Sub-Class | Translation |
| | WO 98/17816 | April 30, 1998 | PCT | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | WO 98/46083 | October 22, 1998 | PCT | | | |
| | WO 99/04026 | January 28, 1999 | PCT | | | |
| | WO 99/15641 | April 1, 1999 | PCT | | | |
| | WO 99/30742 | June 24, 1999 | PCT | | | |
| | WO 99/51754 | October 14, 1999 | PCT | | | |
| | WO 00/65076 | November 2, 2000 | PCT | | | |

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| OTHER DOCUMENTS (continued) | |
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| | Miyoshi, H. et al., "Stable and efficient gene transfer into the retina using an HIV-based lentiviral vector", Proc. Natl. Acad. Sci. USA, 94:10319-10323 (1997) |

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| Examiner | Date Considered |
| EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP §609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant. | |

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| FORM PTO-1449 INFORMATION DISCLOSURE CITATION | Attorney Docket: | Serial No.: |
| | 2026-4287US1 | 09/872,733 |
| | Applicant: | |
| | George Pavlakis | |
| | Filing Date: | Group Art Unit: |
| | June 1, 2001 | 1633 |

| OTHER DOCUMENTS (continued) | |
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| | Miyoshi, H. et al., "Development of a Self-Inactivating Lentivirus Vector", J. Virol., 72:8150-8157 (1998) |
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| | Naldini, L. et al., "In Vivo Gene Delivery and Stable Transduction of Nondividing Cells by a Lentiviral Vector", Science, 272:263-267 (1996) |
| | Naviaux, R.K. et al., "The pCL Vector System: Rapid Production of Helper-Free, High-Titer, Recombinant Retroviruses", J. Virol., 70:5701-5705 (1996) |
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| | Wolff, J.A. et al., "The Cambrian period of nonviral gene delivery", Nature Biotechnology, 16:421-422 (1998) |
| | Zufferey, R. et al., "Multiply attenuated lentiviral vector achieves efficient gene delivery in vivo", Nature Biotechnology, 15:871-875 (1997) |
| | Zufferey, R. et al., "Self-Inactivating Lentivirus Vector for Safe and Efficient In Vivo Gene Delivery", 72:9873-9880 (1998) |
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| Examiner | Date Considered |
| EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP §609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant. | |

PATENT

Docket No. 2026-4287US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : George Pavlakis Group Art Unit: To Be Assigned
Serial No : 09/872,733 Examiner: To Be Assigned
Filed : June 1, 2001
For : MOLECULAR CLONES WITH MUTATED HIV GAG/POL, SIV GAG AND SIV
ENV GENES

INFORMATION DISCLOSURE STATEMENT

ASSISTANT COMMISSIONER FOR PATENTS
Washington, D.C. 20231

Sir:

This Information Disclosure Statement is filed in accordance with 37 C.F.R. §§1.56, 1.97 and 1.98. The items listed on Form PTO-1449, a copy of which is enclosed, may be deemed to be pertinent to the above-identified application and are made of record to assist the Patent and Trademark Office in its examination of this application. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teaching.

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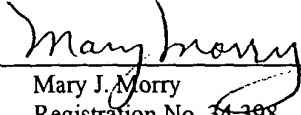
- ☒ 37 C.F.R. §1.97(b)(1), within three months of the filing date of the above-identified application for filing date of the continued prosecution application filed on June 1, 2001; or
- ☐ 37 C.F.R. §1.97(b)(2), within three months of the date of entry into the national stage as set forth in §1.491 in an international application; or
- ☒ 37 C.F.R. §1.97(b)(3), before the mailing date of a first Office Action on the merits, whichever event occurred last.
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- ☐ Charge the fee to Deposit Account No. 13-4500. Order No. _____. A
DUPLICATE COPY OF THIS SHEET IS ATTACHED.
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- a. ☐ one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below; and
- b. ☐ the attached petition requesting consideration of this Information Disclosure Statement; and
- c. ☐ the fee due under 37 C.F.R. §1.17(i)(1) which is paid as set forth in paragraph 10 below.
8. ☐ A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with:
- a. ☐ 37 C.F.R. §1.313(b)(3), after the issue fee has been paid and information cited in this Information Disclosure Statement may render at least one claim unpatentable and is accompanied by the attached Petition To Withdraw Application From Issue;
- b. ☐ 37 C.F.R. §1.313(b)(5), after the issue fee has been paid and information cited in this Information Disclosure Statement is to be considered in a Continuation application upon abandonment of the instant application and is accompanied by the attached Petition To withdraw Application From Issue.
- c. ☐ The fee due under 37 C.F.R. §1.17(i)(1) is paid as set forth in paragraph 10 below.
9. ☐ I hereby certify that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

- ☐ I hereby certify that no item of information in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after make reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.
10. ☐ A check in the amount of \$130.00 is enclosed in payment of the fee due under C.F.R. §1.17(i)(1).
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Respectfully submitted,
MORGAN & FINNEGAN, L.L.P.

Dated: July 16, 2001

By: _____


Mary J. Morry
Registration No. 34,398

CORRESPONDENCE ADDRESS:

MORGAN & FINNEGAN, L.L.P.
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New York, New York 10154
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FORM: IDS.NY
Rev. 05/26/98

| FORM PTO-1449 INFORMATION DISCLOSURE CITATION | | | Attorney Docket: 2026-4287US1 | | Serial No.: 09/872,733 | |
|--|---------------|--------------|----------------------------------|-------|-----------------------------------|-------------|
| | | | Applicant: George Pavlakis | | | |
| | | | Filing Date: June 1, 2001 | | Group Art Unit: To Be Assigned | |
| U.S. PATENT DOCUMENTS | | | | | | |
| Examiner Initial | Patent Number | Issue Date | Name | Class | Sub-Class | Filing Date |
| | 6,174,666 B1 | Jan 16, 2001 | Pavlakis and Felber | | | 3/27/92 |
| | 5,972,596 | Oct 29, 1999 | Pavlakis and Felber | | | 1994 |
| | 5,965,726 | Oct 12, 1999 | Pavlakis and Felber | | | 5/2/97 |
| | 5,786,464 | Jul 28, 1998 | Seed and Haas | | | 7/28/98 |
| | 5,795,737 | Aug 18, 1998 | Seed | | | 9/22/95 |
| | 6,114,148 | Sep 05, 2000 | Seed and Haas | | | |
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| FOREIGN PATENT DOCUMENTS | | | | | | |
|---------------------------------|---------------|--------------|---------|-------|-----------|--|
| Examiner Initial | Patent Number | Issue Date | Country | Class | Sub-Class | Translation |
| | WO 90/11092 | Oct. 1990 | PCT | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | WO 93/20212 | Oct 14, 1993 | PCT | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | WO 96/09378 | Mar 28, 1996 | PCT | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | WO 97/11086 | Mar 27, 1997 | PCT | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | WO 98/12207 | Mar 26, 1998 | PCT | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | WO 98/34640 | Aug 13, 1998 | PCT | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | WO 00/39302 | Jul 6, 2000 | PCT | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | WO 00/39303 | Jul 6, 2000 | PCT | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | WO 00/39304 | Jul 6, 2000 | PCT | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| | WO 99/61596 | Dec. 2, 1999 | PCT | | | <input type="checkbox"/> Yes <input type="checkbox"/> No |

| OTHER DOCUMENTS (continued) | |
|------------------------------------|---|
| | Nappi F, Schneider R, Zolotukhin A, Smulevitch S, Michalowski D, Bear J, Felber BK, and Pavlakis GN. "Identification of a Novel Posttranscriptional Regulatory Element by Using a rev- and RRE-Mutated Human Immunodeficiency Virus Type 1 DNA Proviral Clone as a Molecular Trap." J Virol. 2001 May;75(10):4558-69. |
| | Qiu JT, Liu B, Tian C, Pavlakis GN, Yu XF. "Enhancement of primary and secondary cellular immune responses against human immunodeficiency virus type 1 gag by using DNA expression vectors that target Gag antigen to the secretory pathway." J Virol. 2000 Jul;74(13):5997-6005. |
| | Qiu JT, Song R, Dettenhofer M, Tian C, August T, Felber BK, Pavlakis GN, Yu XF. "Evaluation of novel human immunodeficiency virus type 1 Gag DNA vaccines for protein expression in mammalian cells and induction of immune responses." J Virol. 1999 Nov;73(11):9145-52. |

| | |
|--|-----------------|
| Examiner | Date Considered |
| EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP §609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant. | |

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| FORM PTO-1449 INFORMATION DISCLOSURE CITATION | Attorney Docket: 2026-4287US1 | Serial No.: 09/872,733 |
| | Applicant: George Pavlakis | |
| | Filing Date: June 1, 2001 | Group Art Unit: To Be Assigned |

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